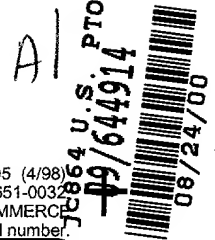


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UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))	Attorney Docket No.	P-4461/2
	First Inventor or Application Identifier	Keane et al.
	Title	SYRINGE TIP CAP
	Express Mail Label No.	EL416965043US

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents	ADDRESS TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
1. <input checked="" type="checkbox"/> * Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original and a duplicate for fee processing) 2. <input checked="" type="checkbox"/> Specification [Total Pages 14] (preferred arrangement set forth below) - Descriptive title of the Invention - Cross References to Related Applications - Statement Regarding Fed sponsored R & D - Reference to Microfiche Appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure 3. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 4] 4. Oath or Declaration [Total Pages 1] a. <input type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> Copy from a prior application (37 C.F.R. § 1.63(d)) (for continuation/divisional with Box 16 completed) i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).	5. <input type="checkbox"/> Microfiche Computer Program (Appendix) 6. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. <input type="checkbox"/> Computer Readable Copy b. <input type="checkbox"/> Paper Copy (identical to computer copy) c. <input type="checkbox"/> Statement verifying identity of above copies
ACCOMPANYING APPLICATION PARTS	
7. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 8. <input type="checkbox"/> 37 C.F.R. § 3.73(b) Statement <input type="checkbox"/> Power of Attorney (when there is an assignee) 9. <input type="checkbox"/> English Translation Document (if applicable) 10. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations 11. <input type="checkbox"/> Preliminary Amendment 12. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 13. <input type="checkbox"/> * Small Entity Statement(s) <input type="checkbox"/> Statement filed in prior application, (PTO/SB/09-12) Status still proper and desired 14. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed) 15. <input checked="" type="checkbox"/> Other: Added Pages For Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed	
* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).	

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: _____ / _____

Prior application information: Examiner _____ Group / Art Unit: _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS
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**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF
PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: SEE 37 C.F.R. § 1.78.

17. Relate Back

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b). For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application, and, if not, the applicant should consider cancelling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

(complete the following, if applicable)

☒ Amend the specification by inserting, before the first line, the following sentence:**A. 35 U.S.C. § 119(e)**

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)". 37 C.F.R., § 1.78(a)(4).

☒ "This application claims the benefit of U.S. Provisional Application(s) No(s).:**APPLICATION NO(S):****FILING DATE**60 / 151,877August 31, 1999 "/ "/ "

UNITED STATES PATENT APPLICATION

OF: Paul Keane, Paul Barkell, Volker Niermann and Sol Green

FOR: SYRINGE TIP CAP

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a syringe tip cap for use in blood collection and transport procedures and more particularly to a syringe tip cap for use with an arterial blood-sampling syringe or whole blood collection syringe.

2. Description of Related Art

Arterial blood samples are commonly obtained from a patient by using an arterial blood gas syringe or a whole blood collection syringe for arterial blood gas or other analytical analysis.

In the field of arterial blood gas syringes, it is important to prevent exposure of a collected blood sample to the atmosphere and to allow for the removal of trapped gases from the syringe once sampling is effected.

Conventional arterial blood gas syringes include a syringe barrel, a syringe tip, a luer connection, a standard needle and a plunger rod with a piston member on the distal end thereof.

When the syringe is being used to draw a blood sample, the needle is conventionally removed after draw and the syringe tip covered by a cap to isolate the sample during storage and/or transportation. Various tip cap structures have been disclosed having features designed to protect both the sample and the technician during capping, transportation and storage. Venting of these prior art structures is performed by

inverting the syringe (tip up), removing the cap and visualizing advancement of the blood sample through the tip consequent to pressure applied to the plunger in order to remove any air left in the syringe tip and then transport the sample to the site of analysis.

While recent advances have contributed to improved technician safety during venting, further improvements are needed, particularly for syringe assemblies intended for arterial blood gas analysis, where residual gas left in a syringe after sampling may interfere with the analysis as well as to protect the user from exposure to the blood sample.

SUMMARY OF THE INVENTION

The present invention is a tip cap for use with an arterial blood gas syringe or whole blood collection syringe. Desirably, the syringe comprises a barrel, a syringe tip, a luer connection, a needle and a plunger rod with a piston member on the distal end of the plunger rod. In instances where the syringe is used to draw a sample by an arterial line, then the needle is not included.

Preferably, the syringe may also include a suitable additive such as an anticoagulant.

The syringe tip is preferably a slightly tapered conical tip projecting from the distal end of the syringe barrel. A passage extends through the syringe tip and communicates with the syringe barrel. The luer connection projects from the distal end of the syringe barrel and coaxially surrounds the syringe tip.

The tip cap preferably comprises a bottom portion, a top portion, and an annular skirt extending from the top portion to the bottom portion having an inner surface and an outer surface. The bottom portion comprises an inner and an outer end wall. The top portion comprises a rim. The annular skirt defines a diameter greater than the outside diameter of the syringe barrel. The outer surface of the annular skirt may include ribs such as protrusions or flats to enhance handling and gripping of the tip cap by the user.

The cap further includes an inner plug that projects proximally from the bottom portion inner end wall and is dimensioned to be telescoped into the passage of the syringe tip of the syringe barrel. The plug provides means to allow air to be vented from the

syringe with depression of the syringe plunger. In addition, the plug provides tactile means to the user to indicate that the syringe has been vented.

The tip cap further comprises an intermediate wall projecting proximally from the inner end wall of the bottom portion of the tip cap and is in spaced surrounding relationship to the plug.

Preferably, the intermediate wall comprises an outer surface that is substantially cylindrical and an inner surface that is defined by six intersecting planar surfaces whereby the inner surface of the intermediate wall is substantially a hexagonal cross-section.

Preferably, the hexagonal cross-sectional of the inner surface of the intermediate wall provides a frictional fit with the conically tapered tip of the syringe. In addition, the outer surface of the intermediate wall preferably comprises vertical interference strips that assist the user in locating the cap onto the syringe, and more particularly whereby the strips engage with the luer connection on the syringe. The strips are of varying lengths to provide tactile feel to the user whereby the increasing resistance between the strips and the luer connection indicates to the user that the tip cap is at various positions. Preferably, the strips are vertical and of varying lengths to identify the venting position. The first position is the venting position and the second position is the secured position or final position whereby the tip cap and the syringe are removably secured.

Additionally, the tip cap further comprises a generally cylindrical internal sealing ring extending from the inner surface of the annular skirt and the inner end wall of the bottom portion. The internal ring further comprises an inner wall surface and outer wall surface. Most preferably, the internal sealing ring is separated from the outer surface of the intermediate wall by a first annular space. In addition, there is a second annular space between the inner surface of the annular skirt and the inner wall surface of the internal sealing ring.

The inner wall surface of the internal sealing ring further comprises indentations or grooves. The indentations provide the means to relieve pressure that may be caused when the syringe tip is pushed into the tip cap. In addition, the indentations may substantially reduce blood leakage from the syringe when the capped syringe is stored in ice water.

In use, the user draws a blood sample from a patient into an arterial blood gas syringe via a needle or intravenous line. Then either the needle is removed from the syringe and placed in a sharps container or the syringe is removed from the IV line. Then the user urges the tip cap over the distal end of the syringe barrel, with a slight twisting motion, whereby the luer connection will cooperate with the strips of the intermediate wall whereby the cap will progressively screw onto the syringe via the cooperation between the luer connection the strips and the plug telescopes into the conical passage of the tip of the syringe barrel. Alternatively, the cap may also be pushed onto the syringe.

The strips provide two stopping points for connecting the tip cap and the syringe. The first stopping point occurs when the user feels the tactile stopping point of the strips. At this first point, a venting position has been reached whereby the user points the syringe tip with the cap upwardly and lightly tapping the syringe barrel to move air bubbles to the distal end of the syringe barrel. The user then gently depresses the plunger so that air bubbles contained within the blood sample will be expelled via the venting mechanism of the plug. When all of the trapped air is removed from the blood sample, a resistance to further depress the plunger will be experienced by the user due to the design of the plug.

The second stopping point occurs when the planar interior surface of the intermediate wall gradually is urged into tight engagement with the outer surface of the conically tapered tip as the tip cap is telescoped onto the syringe barrel. Thus, the plug achieves a sealing of the passage through the tip while the intermediate wall achieves a frictional retention.

Preferably, the cap engages onto at least two of the four thread strips. Thereafter, the cap engages with two more threads, positioned slightly further down. The increase from two to four threads indicates to the user an increase in resistance to turn and therefore indicating the venting position.

The cap and syringe may be separated in a reverse twist off manner by applying a rotational force to the cap. Most preferably, an upward rotational force is applied to the cap and a downwardly force applied to the syringe along the longitudinal axis.

An advantage of the tip cap of the present invention is that it provides the user with tactile feedback when venting of air from the blood sample in the syringe is

substantially complete as well as to visually alert the user that venting is complete.

Still another advantage of the tip cap of the present invention is that there is visual tactile feedback to the user whereby the user can view the syringe tip in the tip cap.

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Another advantage of the tip cap of the present invention is that the outer surface of the tip cap contains features to enhance handling and grip for the user.

10 A notable advantage of the tip cap of the present invention is that the internal ring surrounds the luer connection of the syringe, assists in preventing any residual blood sample in the syringe luer connection from leaking out of the tip cap and luer connection, most notably during storage in ice water.

Another advantage of the present invention is that inclusions of water in the tip cap escape through channels.

A further advantage of the present invention is that the tip cap has a LED light transmission feature due to the structure and materials of construction.

Advantages of the tip cap of the present invention further include the attributes of the intermediate wall and the plug: (i) the strips lock the tip cap into place and substantially prevent the tip cap from being inadvertently removed from the syringe tip; (ii) the strips lock the tip cap into place with the luer connection and prevent the tip cap from being removed laterally from the syringe; (iii) the strips allow ease of use whereby the tip cap is easily screwed or urged into place with the syringe; (iv) the strips and the plug allow the tip cap to be partially seated with the syringe so that the sample in the syringe can be vented; (v) the strips and the plug provide the tip cap to be removable locked with the syringe to prevent accidental detachment of the tip cap and the syringe; (vi) the plug provides the means to vent air from the sample in the syringe without contacting the user; and (vii) the plug allows the syringe to be sealed from the atmosphere.

DESCRIPTION OF THE DRAWINGS

35 FIG. 1 is a perspective view of the tip cap of the present invention.

FIG. 2 is an enlarged cross sectional view of the cap of FIG. 1, taken along line 2-2 thereof.

FIG. 3 is a perspective view of a syringe without the needle.

FIG. 4 is a perspective view of the syringe of FIG. 1 connected to the tip cap of FIG. 2.

FIG. 5 is an enlarged elevational view, partially in section of the syringe and tip cap of FIG. 4, taken along line 5-5 thereof.

DETAILED DESCRIPTION

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 illustrate a tip cap 20 of the present invention.

Cap 20 as shown in FIGS. 1 and 2, has a closed bottom portion 22 having an outer end wall 24 and an inner end wall 26, a top open end 28 having a rim 29 and an annular outer skirt 30 extending from the closed bottom surface to the top open end. Annular skirt 30 includes an inner wall surface 32, an outer wall surface 34 and ribs, flats and/or protrusions 54 on the outer wall surface.

As shown in FIG. 2, tip cap 20 further includes a plug 40 that projects proximally from inner end wall 26 of closed bottom portion 22. Plug 40 is dimensioned to be telescoped into the passage of the syringe tip of a syringe barrel. Plug 40 includes a top end 42, a first end 44, a sidewall 46 extending between top end 42 and first end 44, a bottom end 48, a tapered sidewall 50 extending from first end 44 to bottom end 48 and a flat surface 52 extending vertically along sidewall 46.

As further shown in FIG. 2, a primary internal ring 60 projects proximally from inner end wall 26 and is in spaced surrounding relationship with plug 40. Primary internal ring 60 includes an outer surface 62, an inner surface 64, a bottom section 56, a top section 57, a sidewall 58 extending between bottom section 56 and top section 57. Outer surface 62 of primary internal ring 60 is substantially cylindrical and inner surface 64 is defined by a partial planar surface 66 that includes a plurality of planar surfaces 67

that form a substantially hexagonal cross-section.

Outer surface 62 of primary internal ring 60 further includes a plurality of vertical interference strips 68 of varying lengths, whereby interference strips 63 extend proximally from top section 57 downwardly on outer surface 62 and interference strips 65 extend proximally from bottom section 56 partially upwardly on outer surface 62 at a distance below strips 63.

As further shown in FIG. 2, a secondary internal ring 70 extends from inner wall surface 32 of annular skirt 30 and from inner end wall 26 of closed bottom portion 22. Secondary internal ring 70 is separated from outer surface 62 of primary internal ring 60 by a first annular space 72. Secondary internal ring 70 includes a top section 75, a bottom section 76 and a sidewall 74 extending from the top section to the bottom section. Sidewall 74 includes outer surface 80, inner surface 82 and indentations 84 on inner surface 82. Section compartments 88 are located between outer surface 80 and inner wall surface 32 of annular skirt 30, whereby the compartments are sectioned by sidewalls 86. Sidewalls 86 allow adequate molding conditions.

As shown in FIG. 3, syringe 100 includes a barrel 102 with a distal end 103, a syringe tip 104 and a luer connection 106 located at the distal end of the barrel with an annular space 107 between the syringe tip and the luer connection, a plunger rod 108 with a distal end 110 and a piston member 112 on the distal end of the plunger rod and a passageway 114 that extends through the syringe tip and into the barrel. Syringe tip 104 may be a slightly tapered conical tip.

Once a fluid sample is contained in syringe 100, tip cap 20 is removably secured to syringe 100. The tip cap is screwed onto the luer connection of the syringe whereby the luer connection progressively moves in communication with strips 63, plug 40 moves into communication with the conical tip of the syringe and the luer connection fits into first annular space 72. The movement of the tip cap stops at a first stopping point where the top strips terminate and before the bottom strips begin and at first end 44 of the plug. This first stopping point is easily felt by the user and indicates to the user that a venting position has been reached and that before the cap is removably secured to the syringe, the user should try and remove excess air bubbles from the fluid sample.

At this first stopping position, the user points the syringe tip with the tip cap upwardly whereby the user gently taps the barrel of the syringe to move air bubbles from the fluid sample to the tip of the syringe. The user then gently depresses the plunger so that air bubbles contained within the sample will be expelled through the tip cap via
5 indents 52 of plug 40. When substantially all of the trapped air has been expelled, a resistance to further depress the plunger will be felt by the user, which is an indication that the syringe has been vented.

Then the user proceeds to continue screwing the cap fully onto the syringe,
10 whereby the luer connection further cooperates with the bottom strips on the primary ring and the planar surfaces provide a friction fit with the conically tapered tip of the syringe, whereby the primary is gradually urged into tight engagement with the outer surface of the conically tapered tip. The plug achieves a sealing of the passageway through the tip, whereby the plug fits snugly in the passageway of the syringe tip and with bottom end 48
15 of the plug thereby indicating to the user that the tip cap is securely engaged with the syringe. The removably secured arrangement of the tip cap and the syringe is shown in FIGS. 4 and 5.

As shown in FIGS. 4 and 5, flats 54 are positioned on the outer wall surface of
20 annular skirt 30. The flats substantially prevent the cap from rolling and provide a convenient grasping surface for ready removal and placement of the cap on the syringe. Although a smooth outer circumference without flats is within the purview of the instant invention, a cap with an outer surface with flats is preferred. In addition, outer end wall
25 24 of cap 20 is flat to allow the syringe when connected to the tip cap to be placed on a flat surface unattended, in an upright position thereby allowing ease of manipulation of the syringe by the user.

The tip cap of the invention may be made of a clear molded thermoplastic material so that the syringe tip may be readily viewed in the tip cap. Representative materials
30 include, for example, polyethylene, polypropylene and polyvinyl chloride. Although it is within the purview of the invention to provide caps which are transparent, it is within the purview of this invention to provide caps which are color coded for defining the kind of examination to be conducted on the specimen collected.

35 The syringe may incorporate a hydrophilic material or a silicon may be applied to

the internal surface thereof for enhancing the flow of blood introduced into the syringe.

[illegible]

WHAT IS CLAIMED IS:

1. A tip cap for sealingly covering the distal end of a syringe comprising:
 5 a cylindrical housing having a bottom portion comprising an inner end wall and an outer end wall, a top portion comprising a rim and an annular skirt extending from said top portion to said bottom portion having an inner surface and an outer surface and means for venting air from said syringe and for providing tactile means to the user that said syringe has been vented by said tip cap.
- 10 2. The tip cap of Claim 1, wherein said means for venting is an inner plug that projects proximally from said inner end wall of said bottom portion.
3. The tip cap of Claim 2, further comprising an intermediate wall projecting proximally from said inner end wall of said bottom portion and spaced in surrounding relationship to said plug.
4. The tip cap of Claim 3, wherein said intermediate wall comprises an outer surface that is substantially cylindrical and an inner surface that is defined by intersecting planar surfaces.
5. The tip cap of Claim 4, wherein said inner surface of said intermediate wall is substantially a hexagonal cross-section.
- 25 6. The tip cap of Claim 5, wherein said outer surface of said intermediate wall comprises vertical interference strips.

7. The tip cap of Claim 6, wherein said interference strips comprise a first position to indicate a first venting position to the user and a second position to indicate to the user that said tip cap and said syringe are removably secure.

5 8. The tip cap of Claim 7, further comprising a generally cylindrical internal sealing ring extending from said inner surface of said annular skirt and said inner end wall of said bottom portion.

9. The tip cap of Claim 8, wherein said internal sealing ring comprises an inner wall surface and an outer wall surface.

10 10. The tip cap of Claim 9, wherein said internal sealing ring is separated from said outer surface of said intermediate wall by a first annular space.

11. The tip cap of Claim 10, further comprising a second annular space between said inner surface of said annular skirt and said inner wall surface of said internal sealing ring.

12. The tip cap of Claim 11, further comprising indentations on said inner wall surface of said internal sealing ring.

13. A syringe assembly comprising:

a syringe comprising a barrel, a syringe tip, a luer connection, a needle and a plunger rod with a piston member on the distal end of said plunger rod; and

a tip cap over said distal end of said syringe barrel comprising a cylindrical housing having a bottom portion comprising an inner end wall and an outer end wall, a top portion comprising a rim and an annular skirt extending from said top

portion to said bottom portion having an inner surface and an outer surface and means for venting air from said syringe and for providing tactile means to the user that said syringe has been vented by said tip cap.

- 5 14. The assembly of Claim 13, wherein said means for venting is an inner plug that projects proximally from said inner end wall of said bottom portion.
15. The assembly of Claim 14, further comprising an intermediate wall projecting proximally from said inner end wall of said bottom portion and spaced in
10 surrounding relationship to said plug.
16. The assembly of Claim 15, wherein said intermediate wall comprises an outer surface that is substantially cylindrical and an inner surface that is defined by intersecting planar surfaces.
17. The assembly of Claim 16, wherein said inner surface of said intermediate wall is substantially a hexagonal cross-section.
18. The assembly of Claim 17, wherein said outer surface of said intermediate wall comprises vertical interference strips.
19. The assembly of Claim 18, wherein said interference strips comprise a first position to indicate a first venting position to the user and a second position to indicate to the user that said tip cap and said syringe are removably secure.
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20. The assembly of Claim 19, further comprising a generally cylindrical internal sealing ring extending from said inner surface of said annular skirt and said inner end wall of said bottom portion.
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21. The assembly of Claim 20, wherein said internal sealing ring comprises an inner wall surface and an outer wall surface.
22. The assembly of Claim 21, wherein said internal sealing ring is separated from said outer surface of said intermediate wall by a first annular space.
23. The assembly of Claim 22, further comprising a second annular space between said inner surface of said annular skirt and said inner wall surface of said internal sealing ring.
24. The assembly of Claim 23, further comprising indentations on said inner wall surface of said internal sealing ring.

SYRINGE TIP CAP

ABSTRACT OF THE DISCLOSURE

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The present invention is a syringe tip cap comprising a bottom portion, a top portion, an annular skirt extending therebetween and a plug that projects proximally from the bottom portion so as to be telescoped into the passage of a syringe tip. The plug provides means to allow air to be vented from the syringe with contacting the user. The syringe tip cap of the present invention also provides the user with an indication by tactile and visual feedback that the syringe has been vented.

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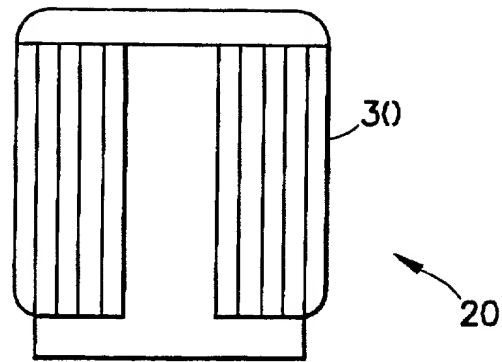


FIG. 1

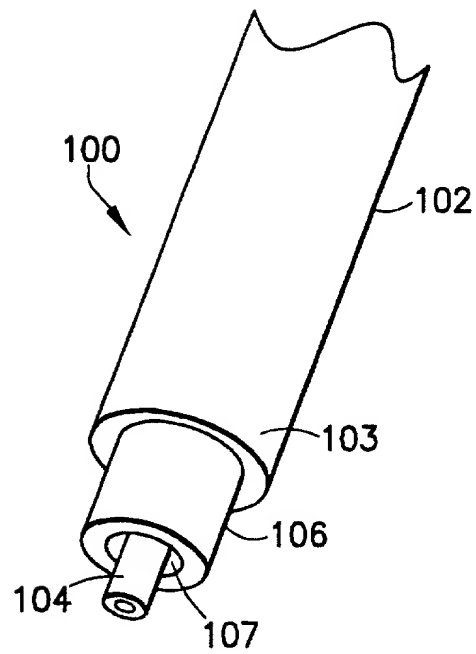


FIG. 3

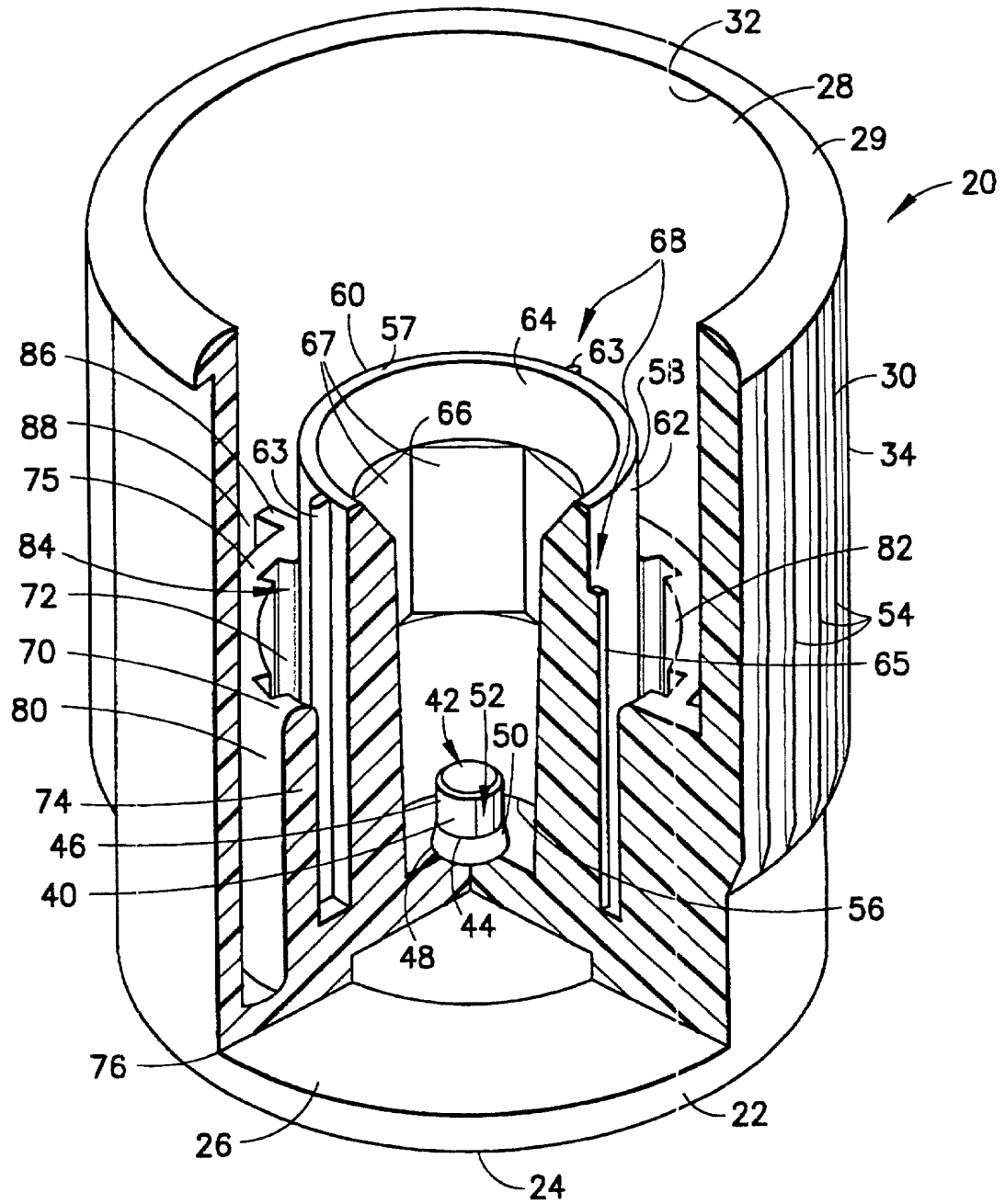


FIG. 2

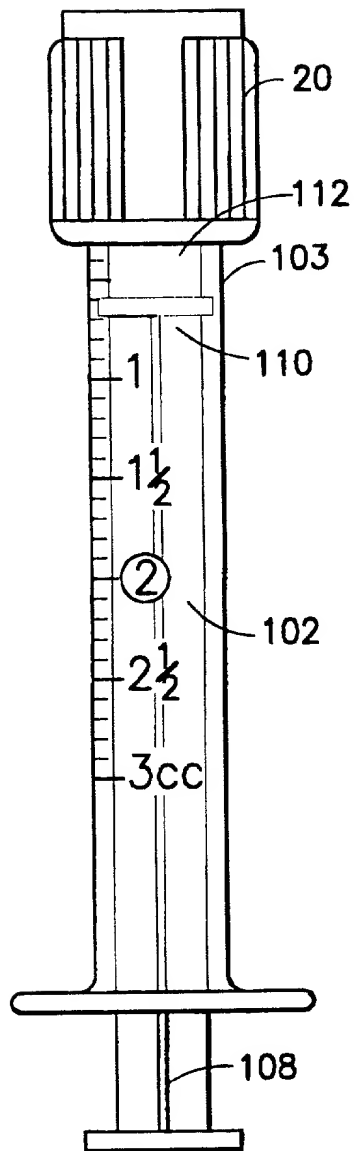


FIG.4

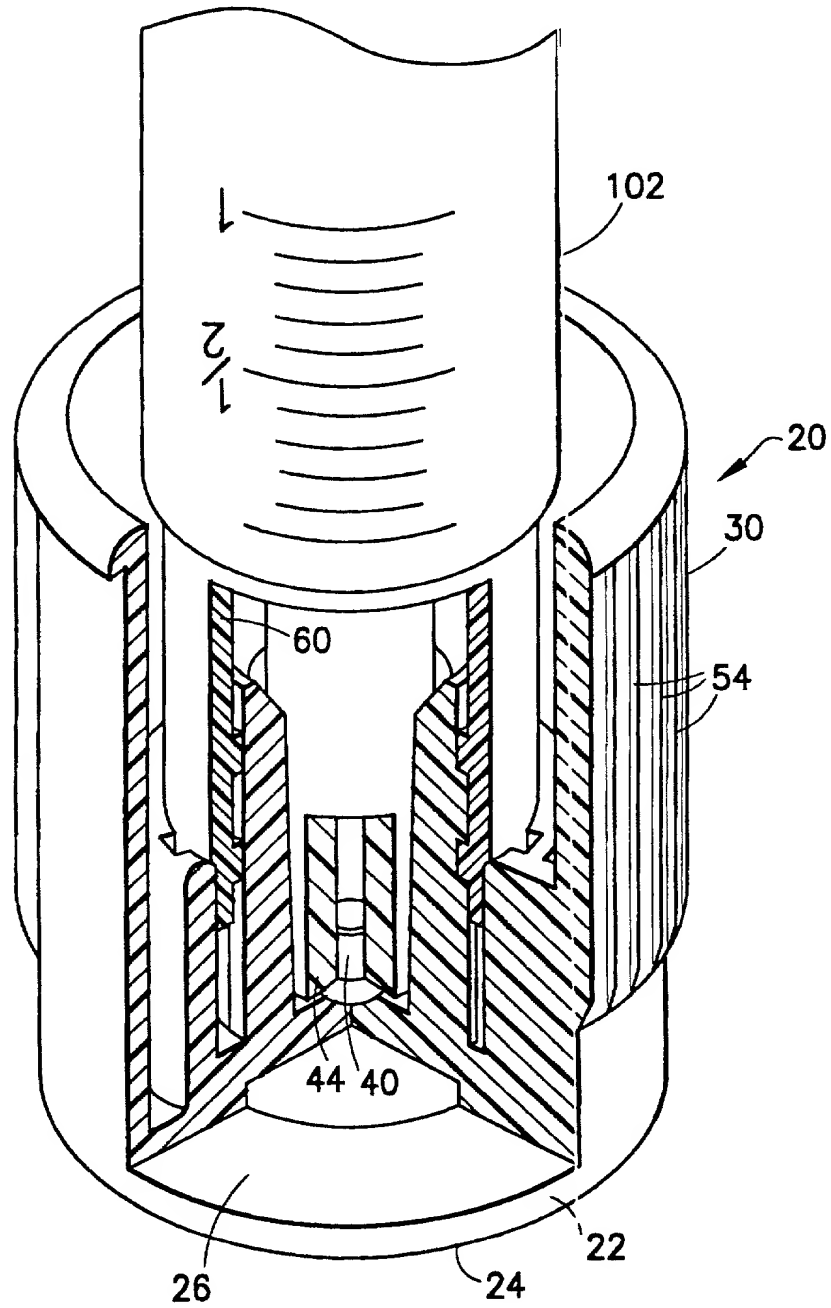


FIG.5